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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,785	02/16/2001	Tadamitsu Kishimoto	046124-5042	1146

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	16

DATE MAILED: 12/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,785	KISHIMOTO ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *1-23 and 25-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The response filed on October 4, 2002 (Paper No. 15) to the restriction requirement of September 4, 2002 has been received. Applicant has elected Group VIII, claim 24 for examination with traverse. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a).

Claims 1-27 are pending.

Claims 1-23, and 25-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim 24 is pending and is currently under examination.

Information Disclosure Statement

It appears that several supplementary information disclosure statements were filed in this application (Paper No. 5 and Paper No. 8). However, only one 1449 form was found in this application (which appears to be the original 1449 form filed with this application) which has been considered and is subsequently attached with this Action. As for the remaining supplementary IDSs, applicant is requested to file (or re-file) the 1449 forms for proper consideration of the references. Clarification is requested.

Specification

The specification is objected to for the following reason: The specification on page 1 should be amended to reflect the priority status of the present application, for example:

This application is a 371 of PCT/JP99/01448 filed March 23, 199 which claims benefit to Japanese Patent Application No. , etc.

The specification is further objected to on page 15, lines 13 and 19 for improper disclosure of amino acid sequences without reference to a sequence identifier (i.e., SEQ ID NO:). Thus, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. This definition sets forth limits, in terms of numbers of amino acids and/or numbers of nucleotides, at or above which compliance with the sequence rules is required. Amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to **mean an unbranched sequence of four or more amino acids.** However, if these sequence represent *portions* of sequences which have been previously disclosed in a computer readable file (CRF), applicant can amend the specification, for example, to read "DTHKSEI", amino acids 12-18 of SEQ ID NO:21. If, however, these sequences have not been previously disclosed in a CRF, applicant must provide a computer readable form (CRF) of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d) (See attached Notice to Comply).

Claim Objections

Claim 24 is objected to for reciting using a substance that "inhibits the action due to CXCR4" to a mammal in need thereof. As written, it is grammatically unclear what the "*action due to* CXCR4" is. This objection may be obviated by amending the claims to recite a method for suppressing vascularization to a mammal in need thereof comprising administering a substance that inhibits CXCR4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Honjo *et al.* (US Patent No. 5,563,048, 1994).

Claim 24 is drawn to a method for suppressing vascularization comprising using a substance that inhibits the action due to CXCR4 to a mammal in need thereof.

Fur the purposes of interpreting the claims, the specification teaches (page 16, lines 11+) that there are no limitations to substances that inhibit the action due to CXCR4. This includes (page 17, line 14+) substances that inhibit SDF-1 from binding to CXCR4 such as anti-SDF-1 antibodies or modified SDF-1 proteins, i.e. SDF-1 "structure-resembling proteins" (specification, page 33, line 10+). As for a "mammal in need thereof", the specification contemplates (page 38,

lines 19+) the administration of the substance to several distinct populations including those having solid tumors, chronic articular rheumatism, psoriasis, and diabetic retinopathy.

Honjo *et al.* broadly teach SDF-1 polypeptides (abstract, and column 1) and the use of such polypeptides as pharmaceutical compositions comprising anti-SDF-1 antibodies or polypeptides of the invention (column 2, lines 64+). Polypeptides of the invention, as defined by Honjo *et al.*, include SDF-1 "structure-resembling" polypeptides (column 3, lines 1+). Honjo *et al.* further teach the use of said polypeptides for disease relating to abnormal proliferation of hematopoietic cells (which reads on the abnormal formation of blood cells such as neovascularization) including use of the polypeptides to a mammal in need thereof wherein said mammals may include members of a populations that have cancer or inflammatory diseases such as rheumatoid arthritis (column 5, line 28; column 6, line 1). Although the prior art does not specifically teach that the use of said substance "suppresses vascularization" or "inhibits the action due to CXCR4", Honjo *et al.* teach the use of such substances to a mammal in need thereof including those populations having cancer or inflammatory conditions such as rheumatoid arthritis. Therefore, such administration of the pharmaceutical compositions comprising anti-SDF-1 antibodies or SDF-1 "structure-resembling" polypeptides would inherently suppress vascularization and inhibit the action due to CXCR4 in a mammal in need thereof. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed substance(s). In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed substance is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d

1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim 24 is further rejected under 35 U.S.C. 102(b) as being anticipated by Arisawa *et al.* (Ann.Surg.Oncol, March 1995, Vol.2, No.2, pages 114-120)

Fur the purposes of interpreting the claims, the specification teaches (page 16, lines 11+) that there are no limitations to substances that inhibit the action due to CXCR4. This includes dexamethasone (page 19, line 21).

Arisawa *et al.* teach a method of suppressing vascularization comprising using a substance (dexamethasone) that inhibits the action due to CXCR4 to a mammal in need thereof. Specifically, Arisawa *et al.* teach that dexamethasone alone inhibits vascularization to a mammal in need thereof (page 120, 1st column, 1st paragraph). Although the prior art does not specifically teach that the use of said substance "inhibits the action due to CXCR4", Arisawa *et al.* teach the use of such a substance to a mammal in need thereof including those populations having cancer. Therefore, administered *in-vivo,* the use of such a substance would inherently inhibit the action due to CXCR4. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed substance(s). In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed substance is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
December 9, 2002